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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,869	07/18/2003	Suresh K. Tikoo	293102003600	2929
25226	7590	04/02/2009	EXAMINER	
MORRISON & FOERSTER LLP			CHEN, STACY BROWN	
755 PAGE MILL RD			ART UNIT	PAPER NUMBER
PALO ALTO, CA 94304-1018			1648	
MAIL DATE		DELIVERY MODE		
04/02/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,869	<b>Applicant(s)</b> TIKOO, SURESH K.
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 09 February 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-26,28-55 and 58-79 is/are pending in the application.  
 4a) Of the above claim(s) 3,5,7,10,16,28,40-55 and 58-64 is/are withdrawn from consideration.  
 5) Claim(s) 1,2,6,12-14,18,19,21,26,30-32,34,36,38,78 and 79 is/are allowed.  
 6) Claim(s) 8,9,11,15,17,20,22-25,29,33,35,37,39 and 65-77 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 18 July 2003 and 22 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-692)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-419)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 9, 2009 has been entered. Claims 1-3, 5-26, 28-55 and 58-73 are pending. Claims 3, 5, 7, 10, 16, 28, 40-55 and 58-64 remain withdrawn from consideration being drawn to non-elected subject matter. Claims 1, 2, 6, 8, 9, 11-15, 17-26, 29-39 and 65-79 are under examination.

### ***Response to Amendment***

2. The following objection(s)/rejection(s) are withdrawn:

- The rejection of claims 30 and 32 under 35 U.S.C. 112, first paragraph, scope of enablement with regard to host cells, is withdrawn in view of Applicant's amendment.
- The rejection of claim 1 under 35 U.S.C. 102(a) as being anticipated by Nielsen *et al.* (US 6,350,853, "Nielsen") is withdrawn in view of Applicant's amendment. The claim is now drawn to a sequence consisting of SEQ ID NO: 414, which is not taught or fairly suggested by Nielsen.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*(Reinstated Rejection)* Claims 8, 9, 11, 15, 17, 20, 22-25, 29, 33, 35, 37, 39, 65-72 and 74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Reddy *et al.* (WO 99/53047, "Reddy"). This rejection was set forth in the Office action of January 22, 2008 and subsequently withdrawn in the Office action of October 8, 2008 in view of an amendment that specified that the encapsidation sequence is within nucleotides 212-531 of PAV3.

However, upon further consideration of the claimed subject matter, the rejection is reinstated. The encapsidation sequence of PAV3 is a natural component of PAV3 and exists whether or not the region has been sequenced. Although Applicant was the first to elucidate this region of the PAV3 genome, the virus itself was already known and disclosed as an adenovirus vector in Reddy's patent. In other words, the recitation of an inherent property of the patented recombinant adenovirus vector is not sufficient to distinguish the instant virus vector from the prior art's virus vector.

Reddy discloses the complete nucleotide sequence of the genome of PAV3, which inherently contains an encapsidation sequence, SEQ ID NO: 414. The genome is used as a vector for expression of heterologous nucleotide sequences, including immunogenic subunits of pathogens (abstract). The vector is also disclosed as being useful for gene therapy purposes (abstract) or gene immunization purposes in combination with pharmaceutical carriers/adjuvants (pages 30-31). Reddy teaches that non-essential regions of the PAV vector may be deleted for inserting heterologous sequences (page 5, first paragraph). Heterologous sequences encode any variety of antigens, including HIV proteins and swine pathogen antigens, such as TGEV S protein (pages 25 and 27). Also disclosed are replication-defective recombinant PAV viruses

(page 5, last paragraph). The PAV3 vectors are expected to contain ITRs from porcine adenovirus. Therefore, the claimed subject matter is anticipated by Reddy.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 73 is rejected under 35 U.S.C. 103(a) as being obvious over Reddy *et al.* (WO 99/53047, "Reddy") as applied to claims 8, 11, 39, 67 and 72 above, and further in view of Letchworth, III *et al.* (US Patent 5,462,734, "Letchworth"). The teachings of Reddy are described above. Reddy suggests the use of the recombinant viruses for expressing heterologous proteins of interest from various pathogens to protect against diseases affecting cattle (page 25-28, and in particular page 29, lines 28-30). Reddy does not specifically suggest any bovine pathogens, however, subunit vaccines for cattle pathogens are known in the art, such as the bovine herpesvirus subunit vaccine of Letchworth. It would have been obvious to incorporate

the subunit from Letchworth's vaccine into Reddy's construct because Reddy suggests the use of subunits (from subunit vaccines) in the PAV construct. Reddy also suggests the use of proteins that will combat disease in cattle (page 29, lines 28-30). One would have had a reasonable expectation of success that the incorporation of Letchworth's subunit into Reddy's PAV construct would have resulted in the expression of the protein because Reddy teaches that the PAV construct is useful for virtually any desired protein (page 25, lines 16-21). Therefore, the invention embodied in claim 73 would have been obvious to one of ordinary skill in the art at the time the invention was made.

***Double Patenting***

5. Claims 8, 9, 11, 15, 17, 20, 22-25, 29, 33, 35, 37, 39, 65-68, 70 and 72 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 and 19-23 of U.S. Patent No. 6,492,343. The patented claims are a species of the instantly claimed genus. Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that at the time of filing the '343 patent, which disclosed the full genomic sequence of PAV3, the encapsidation region had not been fully elucidated. Applicant asserts that because the instant claims now recite the exact sequence responsible for encapsidation that the claims of the patent would not have been obvious.

In response to Applicant's arguments, the Office acknowledges that the patent did not appreciate the exact encapsidation sequence of PAV3. However, the encapsidation sequence of PAV3 is a natural component of PAV3 and exists whether or not the region has been sequenced. Although Applicant was the first to elucidate this region of the PAV3 genome, the virus itself was already known and disclosed as an adenovirus vector. In other words, the recitation of an

inherent property of the patented recombinant adenovirus vector is not sufficient to distinguish the instant virus vector from the patented virus vector.

***Conclusion***

6. Claims 1, 2, 6, 12-14, 18, 19, 21, 26, 30-32, 34, 36 are 38 are allowable. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/  
Primary Examiner, Art Unit 1648